

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES	)	
INTERNATIONAL SRL	)	
a corporation of Barbados,	)	
	)	
Plaintiff,	)	C.A. No. 05-586-GMS
	)	C.A. No. 05-730-GMS
v.	)	C.A. No. 06-620-GMS
	)	CONSOLIDATED
ANDRX PHARMACEUTICALS, LLC	)	
and ANDRX CORPORATION	)	<b>PUBLIC VERSION</b>
	)	
Defendants.	)	

**DEFENDANTS ANDRX PHARMACEUTICALS, LLC'S  
AND ANDRX CORPORATION'S MOTION FOR LEAVE TO FILE FIRST  
AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

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785844 / 30015

Pursuant to Fed. R. Civ. P. 15(a) Defendants Andrx Pharmaceuticals, LLC and Andrx Corporation (collectively, "Andrx") hereby move for leave of this Court to file its First Amended Answer, Affirmative Defenses and Counterclaims on the grounds set forth herein. In compliance with the Court's Local Rules, the proposed Amended Answer, Affirmative Defenses and Counterclaims is attached as Exhibit 1.<sup>1</sup> A black-lined version of the proposed Amended Answer, Affirmative Defenses and Counterclaims showing how it differs from the original filing is attached as Exhibit 2. A proposed order granting Andrx's motion is attached as Exhibit 3.

The proposed amendment adds an affirmative defense of patent unenforceability based on inequitable conduct before the U.S. Patent and Trademark Office ("PTO") during prosecution of the applications leading to the patent-in-suit. The same allegations are also asserted by way of a declaratory judgment counterclaim for unenforceability.

Inequitable conduct is related to fraud and must be pled with particularity pursuant to Rule 9(b) of the Federal Rules of Civil Procedure. Accordingly, it was not until the facts were recently uncovered, developed, and investigated through discovery that Andrx became able to plead this defense with the requisite detail. Andrx has proceeded diligently in seeking from Plaintiff Biovail the discovery that provided the necessary information. Andrx timely noticed depositions of the relevant witnesses, including a named inventor. The first deposition of a witness relevant to the inequitable conduct allegations [REDACTED] was taken on January 15, 2007, and since that time, Andrx has deposed [REDACTED] on February 2, 2007, [REDACTED] February 27, 2007. Through these depositions taken over the past two months, a pattern of misconduct including misrepresentations as to

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<sup>1</sup> Exhibits referenced herein and as referenced in Andrx's Amended Answer, Affirmative Defenses and Counterclaims are provided in the Compendium of Exhibits Volume I and II filed contemporaneously herewith.

properties of prior art formulations, submission of a false and misleading expert affidavit, withholding contrary experimental data, withholding material prior art, and misleading representations as to the operability of alternative pharmaceutical formulations without experimental basis came to light.

Now, having (i) reviewed tens of thousands of pages of documents, and (ii) taken the depositions of the relevant witnesses, Andrx is able to plead its inequitable conduct defense with the requisite particularity. Andrx provided counsel for Biovail a copy of its proposed First Amended Answer on March 12, 2007. On March 19, 2007, Biovail's counsel refused to consent to Andrx's filing the First Amended Answer. This motion follows. The proposed amendment pleads all elements of inequitable conduct, is timely under the circumstances, and will not prejudice Biovail. Accordingly, the Court should grant Andrx's motion.

#### **STATEMENT OF FACTS**

The facts of Andrx's proposed inequitable conduct claim are set forth in paragraphs 27-63 of the Andrx's proposed First Amended Answer and Counterclaim annexed to Andrx's motion as Exhibit 1. Broadly stated, there are five claims of inequitable conduct that are interrelated but each of which would stand on its own, and collectively demonstrate a pattern of misconduct designed to mislead the patent office.

- During prosecution of the '866 patent, individuals having a duty of candor and good faith to the Patent Office misrepresented key teachings of several prior art references in violation of the duty of candor.
- The '866 patent applicants tendered a false and misleading affidavit of Edith Mathiowitz, Ph.D., whom applicants identified as an "expert." However, applicants withheld relevant information from Mathiowitz, and Mathiowitz misrepresented the full scope of the claims to the patent office.
- Applicants withheld internal testing data that directly contradicted arguments made to the patent office to support the patentability of the '866 patent.

- Applicants withheld material prior art from the patent office which directly contradicted arguments made to the patent office to support the patentability of the '866 patent.
- Applicants further misleadingly suggested to the patent office that actual experimental data demonstrated the operability of alternative pharmaceutical formulations when, in fact, no such experiments had ever been conducted.

For all of these reasons, the '866 patent is unenforceable due to inequitable conduct before the patent office.

### ARGUMENT

Leave to amend is freely granted absent delay accompanied by prejudice, bad faith, dilatory motive, or futility. Fed. R. Civ. P. 15(a); *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Howze v. Jones & Laughlin Steel Corp.*, 750 F.2d 1208, 1212 (3d Cir. 1984). Andrx has diligently sought discovery and has urged the Court to set early dates in order to get to trial. Andrx has every reason to seek a prompt disposition, and no reason to delay, because it is subject to a stay of FDA approval pursuant to provisions of the Hatch-Waxman Act governing patent litigation concerning generic drugs.

The elements of inequitable conduct are a failure to disclose material information, submission of false information, or the affirmative misrepresentation of material fact, with an intent to mislead the PTO. See, e.g., *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1128 (Fed. Cir. 2006). As related to fraud, inequitable conduct must be pled with particularity under the Federal Rules of Civil Procedure. See Fed. R. Civ. P. 9(b) ("In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."); see also *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003) ("inequitable conduct, while a broader concept than fraud, must be pled with particularity"); *Inline Connection Corp. v. AOL Time Warner Inc.*, 237 F.R.D. 361, 366-67 (D. Del. 2006) ("The court

recognizes that defendants must plead inequitable conduct with particularity under Rule 9(b)").

Because of the heightened pleading standard, courts have afforded defendants greater leeway to amend later in the case to add inequitable conduct. *See Enzo Life Scis., Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 488-89 (D. Del. 2003) (granting leave to add inequitable conduct claims after depositions of named inventors, even if facts had been available from the public record, because the Rule 9(b) pleading standard made it "prudent and possibly required" for defendant to confirm the facts through discovery); *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys, Inc.*, 989 F. Supp. 1237, 1247 (N.D. Cal. 1997) (granting leave to add inequitable conduct after deposition, and holding that defendant "was entitled to confirm factual allegations before amending to include the inequitable conduct defense"); *Rhone-Poulenc Argo S.A. v. Monsanto Co.*, 73 F. Supp. 2d 537, 539 (M.D.N.C. 1999) (granting leave to add inequitable conduct after close of discovery, even if depositions yielded no new information, because defendant was entitled to investigate through depositions before filing motion).

**1. ANDRX DILIGENTLY SOUGHT DISCOVERY FROM BIOVAIL**

Andrx diligently and timely sought discovery, including the production of prosecution history documents, and depositions of individuals involved in the prosecution of the '866 patent. Biovail sought to delay discovery, necessitating Andrx to file a letter brief with the Court on December 14, 2006. On December 21, 2006, the Court ordered Biovail to make witnesses (including those involved in the prosecution of the '866 patent) available for deposition. Andrx took the depositions of [REDACTED] on January 15, 2007, [REDACTED] on February 2, 2007, and [REDACTED] on February 27, 2007. These depositions enabled Andrx to learn of and confirm the allegations contained in the first amended answer.

2. **ANDRX TIMELY MOVED TO AMEND FOLLOWING THE DEPOSITIONS**

Depositions of relevant Biovail witnesses began only about two months ago. Because inequitable conduct must be pled with particularity, Andrx was entitled to investigate the facts through depositions before moving to amend. *Enxo Life Scis.*, 270 F. Supp. 2d at 489 (observing that it was “prudent and possibly required” for defendant to confirm factual allegations through discovery before seeking leave to add inequitable conduct defense); *Advanced Cardiovascular*, 989 F. Supp. at 1247 (“because the legal theory implicates Federal Rule of Civil Procedure 9(b), requiring pleading of fraud with particularity, [defendant] was entitled to confirm factual allegations before amending to include the inequitable conduct defense”); *Rhone-Poulenc Agro*, 73 F. Supp. 2d at 538-39 (granting leave to amend inequitable conduct claims after close of discovery following depositions, and observing that issue is not whether material information was actually obtained at the depositions, but that defendant acted properly in investigating claim through depositions before making it).

On March 12, 2007, less than two weeks after the deposition of [REDACTED] Andrx sent to Biovail’s counsel its proposed amended answer, and asked Biovail’s counsel for Biovail’s consent to file the amended answer. Today, Biovail’s counsel informed Andrx’s counsel that Biovail would not agree to the filing of Andrx’s proposed amended answer.

3. **BIOVAIL WOULD NOT SUFFER UNDUE PREJUDICE**

Biovail would not be prejudiced by a grant of Andrx’s motion. It is on notice of the bases of the claim from Andrx’s very detailed proposed amendment, and can expect other details to be provided through supplemental responses to interrogatories. *Enxo Life Scis.*, 270 F. Supp. 2d at 489. Further, because the facts at issue are entirely within Biovail’s control, it cannot argue that it needs discovery to mount a defense. *Rhone-Poulenc Agro*, 73 F. Supp. 2d at 539. In the unlikely event that Biovail does need any

such discovery, there is ample time for it to be obtained within the present schedule, because trial is not imminent and Biovail's expert reports on issues where it does not bear the burden of proof are not due until May 9, 2007.

**CONCLUSION**

For the reasons set forth above, Andrx respectfully urges the Court to grant its motion.

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**CERTIFICATE OF SERVICE**

I, Kenneth L. Dorsney, hereby certify that on March 27, 2007, the attached document was hand-delivered on the following persons and was electronically filed with the Clerk of the Court using CM/ECF which will send notification of such filing(s) to the following and the document is available for viewing and downloading from CM/ECF.

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I hereby certify that on March 27, 2007, I have Electronically Mailed the documents to the following non-registered participants:

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